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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Benjamin W. Boldt and Dennis Roscetti**

Serial No.: 09/109,119

Filed: 06/30/98

Group Art Unit: 1653

Examiner: **Jeanine Enewold**

For: **A Process For Detecting A Known Sequence In Genomic DNA**

PRELIMINARY AMENDMENT

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Dear Sir:

This Amendment responds to the Office Action dated May 31, 2000. Kindly amend the application as follows:

In the Claims:

Please amend claims 1, and 13 as follows:

1. (Amended) [A process for testing genomic DNA for conditions, whether inherited or not inherited, comprising:
   a) making a solution comprising the genomic DNA;
   b) adding a primer substantially complementary to a diagnostic section of the genomic DNA, selected from the group consisting of a primer having no mismatch bases and a primer having at least one mismatch base, relative to the diagnostic section;
   c) mixing a DNA polymerase into the solution;
   d) efficiently amplifying the diagnostic section if no mismatch is present;
   e) capturing amplified polynucleotide strands to a solid support; and, detecting captured amplified polynucleotide strands.]

1. A process for testing genomic DNA for conditions, whether inherited or not inherited, comprising:
   a. making a solution comprising the genomic DNA;

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b. adding a primer that hybridizes to a targeted section of the genomic DNA wherein a base at or near the primer 3' end may not hybridize to the genomic DNA;
c. mixing a DNA polymerase into the solution;
d. amplifying the section of the genomic DNA if the base at or near the primer 3' end hybridizes;
e. capturing amplified polynucleotide strands to a solid support;
f. detecting captured amplified polynucleotide strands; and,
g. determining a condition based on a result selected from the group consisting of detection of amplified polynucleotide strands and non-detection of polynucleotide strands.

13. A process for detecting a mismatch base in a diagnostic section of genomic DNA for conditions, whether inherited or not inherited, comprising:
a) obtaining the genomic DNA;
b) mixing the genomic DNA with a primer substantially complementary to the diagnostic section of the genomic DNA, selected from the group consisting of a primer having no mismatch bases and a primer having at least one mismatch base, relative to the diagnostic section;
c) efficiently [selectively] amplifying the diagnostic section from the genomic DNA if no mismatch is present;
d) capturing amplified polynucleotides to a solid support; and quantifying any complex attached to the solid support.

13. A process for detecting a mismatch base in a diagnostic section of genomic DNA for conditions, whether inherited or not inherited, comprising:
a. obtaining the genomic DNA;
b. mixing the genomic DNA with a primer that hybridizes to a targeted section of the genomic DNA wherein a base at or near the primer 3' end may not hybridize to the genomic DNA;
c. amplifying the section of the genomic DNA if the base at or near the primer 3' end hybridizes;
d. capturing amplified polynucleotides to a solid support; and
e. determining a condition based on a result selected from the group consisting of detection of amplified polynucleotide strands and non-detection of polynucleotide strands.

REMARKS

Objection to the Specification under 35 U.S.C. 112:

In the Office Action, on pages 2 and 3, claims 1, 8, 13, 16 and 17 have been rejected under §112.

Applicants have amended independent claims 1 and 13 to remove the terminology considered unclear in the Office Action: "substantially complementary" and "diagnostic section."

Accordingly, Applicants believe that the §112 rejections are obviated by the amendments.

Rejection of claims 1-20 under 35 U.S.C. 102:

Claims 1-20 have been rejected under §102 (e) as being anticipated by Harris et al., U.S. Patent No. 5,849,544.

Applicants have amended independent claims 1 and 13 to state that the primer contains a base at or near the primer 3' end which may not hybridize to the genomic DNA.

Harris et al. performs an amplification that is not dependent upon a base mismatch at or near the 3' end of their primer. In contrast, Applicants' invention is based upon an efficient amplification if no mismatch is present and no or inefficient amplification if at least one mismatch is present. The claims have been amended to illustrate this difference.

Applicants have amended their claims such that their claimed elements are not taught or disclosed by the Harris et al. patent. Therefore, Applicants believe that the rejection has been obviated.

The Office Action's objections and rejections are believed to be overcome by this Amendment and Response. In view of Applicants' amendment and discussion, it is submitted that the claims 1-20 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as EXPRESS MAIL - POST OFFICE TO ADDRESSEE, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on 11/30/00.

M Johnson
Signature